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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/441,061	ENDL ET AL.
	Examiner F. Pierre VanderVegt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 July 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 47-50,55-58,82 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 47-50,55-58,82 and 83 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-46, 51-54 and 59-81 have been canceled.

New claims 82 and 83 have been added.

Claims 47-50, 55-58 and 82-83 are currently pending and are the subject of examination in the present Office Action.

1. In view of Applicant's amendment and remarks filed July 7, 2004, the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 112

2. Claims 47-50, 55-58 and 82-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It was previously stated: "Applicant had amended the claims to recite four MHC Class II complexes comprising a peptide or peptide derivative and to recite that the peptide or peptide derivative must be no more than 25 amino acid residues in length and "comprises" a peptide of 10 contiguous amino acid residues of a selected GAD peptide and asserts that the amendment obviates the ground of rejection. The Examiner respectfully disagrees with Applicant's assessment. Applicant is reminded that the term "comprising" is regarded as open language, meaning that a recitation of a polypeptide comprising a recited amino acid sequence is inclusive of polypeptides/proteins comprising the recited sequence in addition to additional amino acid residues attached to either end. As written, while the claimed peptides require a 'core' of at least 10 contiguous amino acid residues from one of the 23 recited 25-mer, 20-mer or 14-mer peptide sequences, the recitation of a peptide of up to 25 amino acid residues "comprising" that core allows for the inclusion of up to 15 undisclosed amino acid residues or derivative amino acid residues. At a minimum, the recited genus therefore comprises at least 23 (number of claimed peptides with at least a 10-mer core) times 15 (possible number of amino acid residues in addition to the 10-mer core in each peptide) to the 20th power (number of possible different natural amino acid residues that can reside at each of those 15 additional residue sites), or 23×15^{20} different peptides, which calculates to a genus of 7.6×10^{24} different peptides, of which only 23 have been described.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species that are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (MPEP 2163 II.A.3a.ii.). In the present application, this requirement is not met, as a mere recitation of four MHC haplotypes and 23 peptides in the specification and claims does not

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convey possession of the claimed invention, as the genus still encompasses a sizable number of derivatives between 10 and 25 amino acid residues in length and no guidance in regard to which residues should or should not be changed to preserve any particular function.

Therefore, based on the instant description of only 23 peptides, (a peptide consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 2, 3 and 19-39) and no description of the requisite number, position and identities of additional amino acid residues of the claimed genus of peptides or peptide derivatives, the structure of a complex or pharmaceutical composition thereof, wherein said complex comprises "a peptide or peptide derivative derived from glutamic acid decarboxylase which is bound to an allele or a peptide-binding derivative of MHC Class II molecules DR3 or DR4 selected from the group consisting of DR B1 0301, DR B1 0401, DR B1 0402 and DR B1 0404, wherein the peptide or peptide derivative has a length of at most 25 amino acids and comprises a peptide of at least 10 contiguous amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO'S: 2, 3 and 19-39", is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of said complex comprising said peptides encompassed by the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.)"

Applicant's arguments filed July 7, 2004 have been fully considered but they are not persuasive. Applicant has amended the application by replacing claims 46 and 81 with claims 82 and 83. Applicant argues that new claims 82 and 83 are based upon previously objected-to claim 81 and that all other claims are now dependent upon new base claim 82 and should therefore be allowable. However, it is noted that new claims 82 and 83 read upon "peptide derivatives" of glutamic acid decarboxylase (GAD). As stated previously, the instant specification does not provide any descriptive support of peptide derivatives of GAD, only of specific GAD segments and contiguous fragments thereof.

3. Claims 47-50, 55-58 and 82-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated complex comprising a peptide or peptide derivative derived from glutamic acid decarboxylase which is bound to an allele or a peptide-binding derivative of MHC Class II molecules DR3 or DR4 selected from the group consisting of DR B1 0301, DR B1 0401, DR B1 0402 and DR B1 0404, wherein the peptide **consists of** a peptide of at least 6 contiguous amino acids of an amino acid sequence selected from the group consisting of SEQ ID NO'S: 2, 3 and 19-39, does not reasonably provide enablement for the broader recitation of a complex comprising a peptide derivative derived from glutamic acid decarboxylase which is bound to an allele or a peptide-binding derivative of MHC Class II molecules DR3 or DR4 selected from the group consisting of DR B1 0301, DR B1 0401, DR B1 0402 and DR B1 0404. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in the instant claims without an undue

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amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with respect to the extremely large number of peptides broadly encompassed by the claims.

It was previously stated: "Applicant had amended the claims to recite four MHC Class II complexes comprising a peptide or peptide derivative and to recite that the peptide or peptide derivative must be no more than 25 amino acid residues in length and "comprises" a peptide of 10 contiguous amino acid residues of a selected GAD peptide and asserts that the amendment obviates the ground of rejection. Applicant is reminded that the term "comprising" is regarded as open language, meaning that a recitation of a polypeptide comprising a recited amino acid sequence is inclusive of polypeptides/proteins comprising the recited sequence in addition to additional amino acid residues attached to either end. The Examiner respectfully disagrees with Applicant's assessment. As written, while the claimed peptides require a 'core' of at least 10 contiguous amino acid residues from one of the 23 recited 25-mer, 20-mer or 14-mer peptide sequences, the recitation of a peptide of up to 25 amino acid residues "comprising" that core allows for the inclusion of up to 15 undisclosed amino acid residues or derivative amino acid residues. At a minimum, the recited genus therefore comprises at least 23 (number of claimed peptides with at least a 10-mer core) times 15 (possible number of amino acid residues in addition to the 10-mer core in each peptide) to the 20th power (number of possible different natural amino acid residues that can reside at each of those 15 additional residue sites), or 23×15^{20} different peptides, which calculates to a genus of 7.6×10^{24} different peptides, of which only 23 have been described.

Applicant's claims are drawn to an extremely large genus of peptides and peptide derivatives. However, the instant specification only discloses how to make 23 of those peptides and fragments thereof that are at least 10 contiguous amino acids in length. Other than the amino acid residues that are comprised within the sequences of SEQ ID NOs: 2, 3 and 19-39, the specification does not disclose what amino acid residues would be acceptable as part of the 10-25-mer peptide sequences.

Further, the scope of the claims encompasses the addition of unspecified amino acid residues to the at least 10-mer peptide fragments of SEQ ID NOs: 2, 3, 19-38 or 39. The skilled artisan can make fragments *limited to subsequences* of SEQ ID NOs: 2, 3 and 19-39 without undue experimentation. However, before the skilled artisan can make polypeptides comprising a 10-mer of SEQ ID NOs: 2, 3 and 19-39 with additional flanking amino acid residues that are not part of SEQ ID NOs: 2, 3 and 19-39, guidance is required with respect to the identity of those flanking residues. In the instant case however, the specification does not appear to provide this needed guidance. Therefore the scope of the instant claims encompassing peptides or peptide derivatives of up to 25 amino acids in length and comprising at least 10 contiguous amino acid residues of SEQ ID NOs: 2, 3, 19-38 or 39 does not appear to be commensurate with the enablement provided by the instant disclosure.

In view of the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute."

Applicant argues that new claims 82 and 83 are based upon previously objected-to claim 81 and that all other claims are now dependent upon new base claim 82 and should therefore be allowable. However, it is noted that new claims 82 and 83 read upon "peptide derivatives" of glutamic acid decarboxylase (GAD). As stated previously, the instant specification does not teach the artisan how to make and use the full scope of what is encompassed by the recitation of "peptide derivatives" of GAD, but is enabling only for specific GAD segments and contiguous fragments thereof.

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Conclusion

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. ✓
Patent Examiner
October 18, 2004

Pat J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
10/18/04